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K001318

SMITHS INDUSTRIES
Medical Systems

SIMS Portex Inc.

10 Bowman Drive
PO Box 0724
Keene NH 03431 USA
Telephone: 603-352-3812
Fax: 603-352-3703

H: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

510(K) SUMMARY:

COMPANY INFORMATION:

SIMS Portex Inc
10 Bowman Drive
Keene, NH 03431
(603) 352-3812
Contact: Brian D. Farias
Regulatory Affairs Specialist

PREPARATION DATE OF SUMMARY:

April 25, 2000

TRADE NAME:

CPAP SYSTEM

COMMON NAME:

CPAP SYSTEM for use with Endobronchial Tubes

PRODUCT CLASS/CLASSIFICATION:

Class II, 73 BYE, 21 CFR 868.5965 (CPAP SYSTEM)
Class II, 73 CBI, 21 CFR 868.5740 (Endobronchial tube)

PREDICATE DEVICE(S):

Mallinckrodt Medical CPAP SYSTEM (K912240)

Vital Signs Inc. EASY-PAP™ One-Lung CPAP Device (510[k] Unknown)

DESCRIPTION:

The SIMS CPAP SYSTEM is a Continuous Positive Airway Pressure System, with or without a Blue Line® Endobronchial Tube. The system consist of: (1) one liter non-latex reservoir bag, (2) slide valve assembly, (3) Washington tee, (4) single axis swivel, (5) 10' star lumen vinyl tubing, (6) oxygen line vinyl tip, (7) oxygen line proximal adapter, (8) disposable manometer.

INDICATIONS FOR USE

The SIMS Portex CPAP SYSTEM is indicated for delivering continuous positive airway pressure (CPAP) to the non-ventilated, non-dependent lung during thoracic surgery and one-lung anesthesia.

The SIMS Portex CPAP SYSTEM is indicated for both the prevention and treatment of hypoxemia during one-lung anesthesia utilizing an endobronchial tube. Additionally, the use of CPAP during one-lung anesthesia may improve exposure of the surgical field, allowing the identification of intralobar planes during pulmonary resection.

TECHNICAL CHARACTERISTICS:

The SIMS CPAP SYSTEM is comprised of similar components and materials as the predicate devices and all of the components used are legally marketed devices, marketed separately and/or contained in legally marketed devices, for airway management applications. The SIMS proposed device, like the Vital Signs predicate device, is non-sterile.

NON-CLINICAL DATA:

The data submitted demonstrates that the proposed SIMS Portex CPAP SYSTEM performs equivalently to the Mallinckrodt Medical predicate device. Testing completed shows that both devices have similar recovery times and that both devices are stable at high and low CPAP settings.

CLINICAL DATA:

Not applicable

CONCLUSION:

The comparison to the predicate device demonstrates that the proposed device is safe and effective and is substantially equivalent to the predicate device.

Very truly yours,

SIMS PORTEX INC.

Brian D. Farias
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 0 2000

Mr. Brian D. Farias
SIMS Portex Inc.
10 Bowman Drive
P.O. Box 0724
Keene, NH 03431

Re: K001318
CPAP System for use with Endobronchial Tubes
Regulatory Class: II (two)
Product Code: BYE, CBI
Dated: April 25, 2000
Received: April 26, 2000

Dear Mr. Farias:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B: INTENDED USE OF DEVICE

PROPOSED INDICATIONS FOR USE:

510(k) Number K001318

Device Name: CPAP SYSTEM for use with Endobrochial Tubes

Indications For Use:

The SIMS Portex CPAP SYSTEM is indicated for delivering continuous positive airway pressure (CPAP) to the non-ventilated, non-dependent lung during thoracic surgery and one-lung anesthesia utilizing an endobronchial tube.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

Division of Cardiovascular & Respiratory Devices

510(k) Number K001318

Prescription Use ✓ OR Over-The-Counter Use _____